DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 29, 2015

Terumo Cardiovascular Systems Corporation
Garry A. Courtney
Director, Regulatory Affairs
28 Howe Street
Ashland, Massachusetts 01721

Re: K142500
Trade/Device Name: One Way Soft Valve
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: MJJ
Dated: January 2, 2015
Received: January 5, 2015

Dear Garry A. Courtney,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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SECTION 4 – Indications for Use

One Way Soft Valve

510(k) Number (if known): K **142500**

Device Name: One Way Soft Valve

Indications For Use:

The One Way Soft Valve is intended to be used for the prevention of retrograde flow in ¼" or smaller lines subject to arterial pressure during cardiopulmonary bypass procedures for use up to six hours.

Prescription Use **XX** OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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SECTION 5 – 510(k) Summary
One Way Soft Valve

Submitter Information:

This submission was prepared in August 2014 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
28 Howe Street
Ashland, MA 01721
Facility Registration No. 1212122

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
One Way Soft Valve	Cardiopulmonary Bypass Blood Reservoir (ProCode: MJJ)	CPB Check Valve, Retrograde Flow, In-Line

Identification of Predicate Device:

The device submitted in this 510(k) maintains characteristics that are substantially equivalent in indications for use, design, technology including features, materials, and principles of operation to the Quest Medical Retroguard Arterial Safety Valve – K922356.

Device Description:

The One Way Soft Valve is a transparent one-way valve with ¼" inlet and outlet ports. The One Way Soft Valve prevents retrograde flow. A directional arrow is printed on the valve to provide the user with a visual indication of the allowable flow direction within the valve. The valve is constructed entirely of PVC and is to be used in lines subject to arterial pressures.

Comparison of Indication

The One Way Soft Valve product and the predicate, Quest Medical Retroguard Arterial Safety Valve product, are intended to be used to prevent retrograde flow during cardiopulmonary bypass procedures for up to six hours.

Subject Device Indication: The One Way Soft Valve is intended to be used for the prevention of retrograde flow in ¼" or smaller lines subject to arterial pressure during cardiopulmonary bypass procedures for use up to six hours.

Predicate Device Indication: Per the IFU, the Quest Medical Retroguard Arterial Safety Valve is "for prevention of retrograde flow when used with centrifugal pump."

The differences between the intended use for the subject device and the predicate device do not constitute a new intended use. The wording differences are details of device specifications (e.g. dimensions), specified circuit placement (e.g. lines subject to arterial pressures, line size), and

circuit component choices (e.g. pump choice), which do not significantly impact the overall intended use of the valves in preventing retrograde flow during cardiopulmonary bypass procedures. These differences are not critical to the overall intended use of the device – preventing retrograde flow during cardiopulmonary bypass procedures. Additionally, the differences do not affect the safety and effectiveness of the device when used as labeled. Performance testing was conducted with substantially equivalent results and is presented in this submission.

Principles of Operation, Technology, and Design:
The One Way Soft Valve is a single-use, disposable device that prevents retrograde flow in lines subject to arterial pressure by utilizing a closed path, mechanical, one-way valve. The design allows flow through the valve in one-direction and limits the flow in the opposing direction. The operating principles of the Quest Medical Retroguard Arterial Safety Valve are identical to that of the device subject to this submission, the One Way Soft Valve.

The primary differences in design between the One Way Soft Valve and the predicate device are found in the material selection, the type of check-valve used, port dimensions, and overall prime volume.

- The first of these differences is the material choice. The One Way Soft Valve is constructed of a flexible PVC housing and a flexible PVC valve, while the predicate valve is constructed of a rigid ABS housing and flexible silicone valve. Flexible Polyvinylchloride (PVC) is a common material used in Cardiopulmonary Bypass Circuits. Performance testing results are presented within this submission. The subject devices were tested to clinically relevant pressures to ensure that they could withstand both positive and negative pressures and still maintain desired performance.
- The second difference is the type of check-valve used. The One Way Soft Valve uses a sleeve-like valve, while the predicate uses a duckbill valve design. Both designs allow flow through the valve in one-direction and limit flow in the opposing direction.
- The third difference is the adapter (or port) dimensions. The One Way Soft Valve has a smaller port size (1/4" compared to 3/8"), which allows the One Way Soft Valve to be used in smaller diameter lines.
- Lastly, the One Way Soft Valve has a smaller prime volume than the predicate device. The One Way Soft Valve has a prime volume of approximately 9 mL. The predicate device has a prime volume of approximately 20 mL. Submission of this 510(k) was primarily motivated by the clinical need for a smaller, more versatile valve for use in Cardiovascular Procedure Convenience Kits.

Testing was completed that demonstrates the One Way Soft Valve is as safe and effective as the predicate. Any differences in design between the One Way Soft Valve and the predicate do not raise different questions of safety and effectiveness.

Performance Evaluations:
Terumo Cardiovascular Systems has conducted *in-vitro* performance evaluations for the purpose of demonstrating that the One Way Soft Valve device is *substantially equivalent* to the predicate Quest Medical Retroguard Arterial Safety Valve.

Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- One Way Soft Valve Tubing Connection (Bond) Strength Evaluation
- One Way Soft Valve Mechanical/Structural Integrity/Burst Strength Evaluation
- One Way Soft Valve Opening Pressure Evaluation
- One Way Soft Valve Negative Pressures and Retrograde Flow Evaluation
- One Way Soft Valve Circulation and Hemolysis Evaluation

The Terumo Cardiovascular Systems Corporation One Way Soft Valve exhibits substantially equivalent performance to the predicate, the Quest Medical Retroguard Arterial Safety Valve– K922356. Performance testing was conducted with substantially equivalent results and is presented in this submission.

Substantial Equivalence Statement:
The One Way Soft Valve device and the predicate device, the Quest Medical Retroguard Arterial Safety Valve – K922356, are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject device and the predicate devices do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed the maximum residue limits at the time of product distribution.

- Terumo maintains biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

Conclusion:
In summary, Terumo deems the Terumo Cardiovascular Systems Corporation One Way Soft Valve device is substantially equivalent to the predicate device, the Quest Medical Retroguard Arterial Safety Valve – K922356, with respect to intended use, duration of use, design, materials, principles of operation, and performance. It is further noted that any recognized differences do not raise any new issues of patient/user safety or product effectiveness.